DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 30, 2015

CenterVue S.p.A.
Mr. Roberto Gabriotti
QA/RA Manager
via San Marco, 9h
35129 Padova, Italy

Re: K150320
Trade/Device Name: COMPASS
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC, HPT
Dated: May 15, 2015
Received: May 20, 2015

Dear Mr. Gabriotti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

510(k) Number K150320

Device Name

COMPASS

Indications for Use *(Describe)*

The CenterVue COMPASS is intended for taking digital images of a human retina without the use of a mydriatic agent and for measuring retinal sensitivity, fixation stability and the locus of fixation. It contains a reference database that is a quantitative tool for the comparison of retinal sensitivity to a database of known normal subjects.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Jan C. Callaway -S
2015.06.19
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510(k) Summary in accordance with 21 CFR 807.92

Device Name:	CenterVue COMPASS
Type of submission:	Traditional
Date of submission:	2 February 2015
Manufacturer:	CENTERVUE SPA Via San Marco 9H 35129 Padova - ITALY
510(k) Owner:	CENTERVUE SPA Via San Marco 9H 35129 Padova - ITALY
Phone Fax	+39 049 7396 147 +39 049 7396 148
510(k) submitter and contact	Mr. Roberto Gabriotti Centervue S.p.A. Manager of Quality and Regulatory Affairs Via San Marco 9H, 35129 Padova - ITALY Phone: +39 049 7396 147 Fax: +39 049 7396 148 Email: roberto.gabriotti@centervue.com
FDA Product Code:	MYC; HPT
FDA Regulation Number:	21 CFR 886.1570; 886.1605
FDA Classification Name:	Ophthalmoscope, laser, scanning; Perimeter, Automatic, Ac-powered
Common Name:	Ophthalmoscope; Perimeter
FDA Panel:	Ophthalmology
FDA Classification:	Class II
FDA Identification:	An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye. A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light
Indications for Use:	The CenterVue COMPASS is intended for taking digital images of a human retina without the use of a mydriatic agent and for measuring retinal sensitivity, fixation stability and the locus of fixation. It contains a reference database that is a quantitative tool for the comparison of retinal sensitivity to a database of known normal subjects.

DEVICE DESCRIPTION

The CenterVue COMPASS is a scanning ophthalmoscope combined with an automatic perimeter that allows the acquisition of images of the retina, as well as the measurement of retinal threshold sensitivity and the analysis of fixation. The device works with a dedicated software application, operates as a standalone unit, integrates a dedicated tablet, a joystick, a push-button and is provided with an external power supply.
COMPASS operates in non-mydriatic conditions, i.e. without the need of pharmacological dilation and is intended for prescription use only.

The Centervue COMPASS device operates on the following principles:

- An anterior segment alignment system is included, which uses two infrared LEDs with a centroid wavelength of 940 nm and two cameras, whereas the former illuminate the external eye by diffusion and the latter allow a stereoscopic reconstruction of the pupil's position, used for automated alignment purposes via pupil tracking;
- An infrared imaging system captures live monochromatic images of the central retina over a circular field of view of 60° in diameter, by an horizontal line from an infrared LED with a centroid wavelength of 850 nm and by an oscillating mirror which scans the line to uniformly illuminate the retina; such images are in turn used for auto-focusing purposes and to track eye movements, providing a measure of a patient's fixation characteristics and allowing active compensation of the position of perimetric stimuli;
- A concurrent color imaging system allows the capture of color images of the central retina over a circular field of view of 60° in diameter, using a white LED and a blue LED combined to obtain a white light illuminating the retina by the same scan mechanism;
- A fixation target projector, projecting onto the retina a fixation target obtained from a green LED;
- A stimuli projector, projecting onto the retina white light Goldmann stimuli at variable intensity and allowing measurements of threshold sensitivity at multiple locations, according to a patient's subjective response to the light stimulus projected at a certain location.

The COMPASS device interacts with the patient by directing infrared, white, blue and green wavelength illumination into the patient's eye and by recording a patient's confirmation that a certain light stimulus has been perceived or not.

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TECHNICAL SPECIFICATIONS

FundusPerimetry:

- Projection field: 30° (radius)
- Background luminance: 31.4 asb
- Maximum luminance: 10000 asb
- Dynamic range: 0 - 50 dB
- Stimulus size: Goldmann III
- Stimulus duration: 200 ms
- Fixation control: 25 Hz automated retinal tracking

FundusImaging:

- Field of view: 60° (diameter)
- Sensor resolution: 5 MPixel (2592x1944)
- Light source: infrared (825-870 nm) and white LED (440-650 nm)
- Imaging modalities: color, infrared, red-free

Otherfeatures:

- Non-mydriatic operation: minimum pupil size 3 mm
- Auto-focus range: -12D to +15D

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PREDICATE DEVICES

The predicate devices selected for comparison with the CenterVue COMPASS are:

Predicate Device 1 (primary):	MAIA
510(k) Owner:	CenterVue
510(k) Number:	K133758
Clearance Date:	2014-04-23
FDA Product Code 1:	HPT
Classification Name 1:	Perimeter, Automatic, Ac-powered
Regulation Number 1:	886.1605
Product Code 2:	HLI
Classification Name 2:	Ophthalmoscope, Ac-powered
Regulation Number 2:	886.1570

Predicate Device 2:	EIDON
510(k) Owner:	CenterVue
510(k) Number:	K142047
Clearance Date:	2014-11-12
FDA Product Code:	MYC
Classification Name:	Ophthalmoscope, Laser, Scanning
Regulation Number:	886.1570

Predicate Device 3:	Humphrey Field Analyzer (HFA-II), model 720
510(k) Owner:	Carl Zeiss, Inc.
510(k) Number:	K954167
Clearance Date:	1995-11-24
FDA Product Code:	HPT
Classification Name:	Perimeter, Automatic, Ac-powered
Regulation Number:	886.1605

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE(S)

Fundus Perimetry is the technological principle for both the subject and primary predicate device. It is based on continuous imaging of the retina using infrared illumination, to enable compensation of eye movements during perimetry. At a high level, the subject and primary predicate device are based on the same technological elements.

The following technological differences exist between the subject and primary predicate device:

Difference	Equivalence discussion
Capabilities for color and red-free imaging	No additional concern in terms of safety and effectiveness as the device is equivalent to EIDON in this respect
Modified optics for wider imaging field	No additional concern in terms of safety and effectiveness as the device is equivalent to EIDON in this respect
Use of visible light source for color and red-free imaging	No additional concern in terms of safety and effectiveness as the device is equivalent to EIDON in this respect
Use of additional infrared light source for alignment	No additional concern in terms of safety and effectiveness as the device is equivalent to EIDON in this respect
Modified optics for wider perimetry measurement field	No new concerns for safety and effectiveness vs. the primary predicate device as differences represent a performance improvement
Luminance parameters and measurement range	Differences are due to the adoption of Humphrey perimetric standards for luminance. No new concerns for safety and effectiveness as the device is equivalent to the Humphrey HFA-II in this respect
Presence of anterior eye imaging system used for patient alignment	No additional concern in terms of safety and effectiveness as the device is equivalent to EIDON in this respect
Use of green fixation target (instead of red)	No additional concern in terms of safety and effectiveness as the device is equivalent to EIDON in this respect

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

<u>Electricalsafetyandelectromagneticcompatibility(EMC)</u>

The device complies with the IEC 60601-1:2005 standard for safety and with the IEC 60601-1-2:2007 standard for EMC.

<u>SoftwareVerificationandValidationTesting</u>

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury. The software also complies with the IEC 62304 standard for software life cycle processes.

Perimetersstandardtesting

The device complies with the ISO 12866:1999 standard for perimeters.

Lighthazardtesting

The device complies with the ISO 15004-1:2006 standard for ophthalmic instruments and with the ISO 15004-2:2007 standard for light hazard protection.

Clinicaltesting

Measurements have been obtained with the CenterVue COMPASS and with the Humphrey HFA-II on 200 normal subjects and on 120 subjects with pathology affecting the visual field (in particular glaucoma) to support equivalence. Subjects' age ranged from 20 to 86 years (58.5 ± 16.7).

Perimetric settings used for the measurements with both devices were:

- stimuli locations: 24-2 grid;
- threshold strategy: 4-2 (or full threshold) for COMPASS and SITA standard for HFA-II;
- stimulus size: Goldmann III;
- stimulus color: white;
- stimulus duration: 200 msec.;
- background luminance: 31.4 asb;
- maximum luminance: 10,000 asb.

Mean differences in thresholds between the Centervue COMPASS and the Humphrey HFA-II in both subjects groups were found to be equivalent to those reported for the Humphrey HFA between SITA Standard and full threshold. No adverse event was reported during the study. This demonstrates equivalence of the subject device to the predicate in terms of effectiveness.

REFERENCE DATABASE

The COMPASS reference database was developed by obtaining threshold sensitivity data from 200 eyes of 200 normal subjects. Age range of the measured population was 20 - 86 (50.6 ± 15.2).
The perimetric settings used for the measurements were:

- stimuli locations: 24-2 grid
- threshold strategy: 4-2
- stimulus size: Goldmann III
- stimulus color: white
- stimulus duration: 200 msec.
- background luminance: 31.4 asb
- maximum luminance: 10,000 asb

The reference database is only available for the 24-2 test grid.

CONCLUSIONS

Based on the information contained within this submission, it is concluded that the CenterVue COMPASS is substantially equivalent to the identified predicate devices already in interstate commerce within the USA.